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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DOWE, KATHERINE MARIE	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,511	SUNDAR, RANGARAJAN	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9-28,30 and 32-39* is/are pending in the application.

4a) Of the above claim(s) *11-28,30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9,10 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is in response to the amendment filed September 22, 2010.

2. Claims 1, 4-6, 9, 10, and 33-39 are currently pending and claims 11-28, 30, 32 have been withdrawn.

Claim Rejections - 35 USC § 112

3. The rejections of claims 2 and 7 under 35 U.S.C. 112, first and second paragraphs, as set forth in the previous Office Action are moot in view of Applicant's cancellation of the claims.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38 and 39 each recite "the coating demonstrates substantially no loss of adhesion under an ASTM D-3359 cross hatch adhesion test". There is insufficient support in the disclosure for this limitation. The disclosure recites the *silane layer* improves adhesion of the polymer coating. The coating samples treated with the amino silane layer suffered neglible loss of adhesion, while the same coating without amino silane treatment showed a significant amount of adhesion failure between the polymer coating and the stainless steel (specification page 11).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 38 and 39 each recite "the coating demonstrates substantially no loss of adhesion under an ASTM D-3359 cross hatch adhesion test". It is unclear what type of "adhesion" the claim is referring to. For the purpose of examination, the claim is interpreted such that substantially no adhesion failure occurs between the silane treated polymer coating and the stainless steel of the stent.

Double Patenting

8. Claims 1, 4-6, 9, 10, and 33-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50 of copending Application No. 10/827,817, as amended October 22, 2010. For double patenting to exist as between the rejected claims and copending application claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50, it must be determined that the rejected claims are not patentably distinct from claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50 and, if so, whether those differences render the claims patentably distinct.

Claims 1, 4-6, 9, 10, and 33-37 recite a "catheter" (see for example, line 2 of claim 1 of the copending application as amended October 22, 2010), a balloon operably attached to the catheter" (see line 3 of claim 1 of the copending application), "a stent disposed on the balloon" (see line 4 of claim 1 of the patent), "a silane layer" (see lines 9-12 of claim 1 of the copending

application), and "a coating disposed on the silane layer" (see lines 7-8 of claim 1 of the copending application).

It is clear that all the elements of claims 1, 4-6, 9, 10, and 33-37 are to be found in claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50. The difference between claims 1, 4-6, 9, 10, and 33-37 of the application and claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50 of the copending application lies in the fact that the copending application claim includes many more elements and is thus much more specific. Thus the invention of claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50 is in effect a "species" of the "generic" invention of claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 4-6, 9, 10, and 33-37 are anticipated by claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50 of the copending application, they are not patentably distinct from claims 1, 4, 5, 8, 10, 13, 14, 20, 34, 35, 38, 39, 42, 43, 45, 46, 49, and 50.

Regarding claims 38 and 39, the instant application teaches the silane layer improves the adhesion of the polymer coating such that experimental samples treated with amino silane suffered a negligible loss of adhesion between the polymer coating and the stainless steel of the stent (instant specification, page 11). Therefore, it would have been obvious that the coating in the copending application, which is also treated with amino silane (see lines 9-12 of claim 1 of the copending application), would too demonstrate substantially no loss of adhesion under an ASTM D-3359 cross hatch adhesion test.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1, 4-6, 9, 10, 33, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,356,433) in view of Yan (US 6,240,616). Regarding claims 1, 4-6, 9, 10 33, 36, and 37, Rowland discloses the invention substantially as claimed including a stent disposed on a balloon catheter (col 2, ll 64-68). The stent comprises a stainless steel frame (col 4, ll 35-39) and an amino silane layer disposed on the stent for binding biologically active agents (col 4, ll 40-62). However, Rowland does not disclose a coating disposed on the silane layer, wherein the coating is a non-biologically active polymer including polycaprolactone (PCL). Yan discloses a stent and teaches a coating (100) may be applied to the external surface, wherein the coating is a non-biologically active polymer including polycaprolactone (PCL). Yan teaches the polymer coating "is bioabsorbable, but no therapeutic agent is loaded into the polymer. The coating 100 dissolves after implantation and this delays the time that a therapeutic agent is released into the vasculature of the patient." (col 9, ll 22-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that a non-biologically active polymer layer including PCL was disposed over the silane layer to control the release rate of the biologically active agents attached to the amino-silane layer.

Regarding claims 38 and 39, the instant application teaches the silane layer improves the adhesion of the polymer coating such that experimental samples treated with amino silane suffered a negligible loss of adhesion between the polymer coating and the stainless steel of the stent (instant specification, page 11). Therefore, it would have been obvious that the coating in the combination of Rowland and Yan would also demonstrate substantially no loss of adhesion

under an ASTM D-3359 cross hatch adhesion test, since the coating is disposed over an amino silane layer (col 4, ll 40-62).

12. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,356,433) and Yan (US 6,240,616), as applied to claims 1 and 6 above, further in view of Sagiv (US 4,539,061). Rowland discloses the invention substantially as claimed as shown above. However, Rowland does not disclose the thickness of the silane layer. Sagiv discloses a similar system comprising a substrate layer (col 3, ll 26-33; analogous to the stent of Rowland), an intermediate silane layer (col 4, ll 13-15), and biologically active compound coupled to the surface of the intermediate layer (col 6, ll 45-47). The intermediate layer is formed as a monolayer with individual monolayers formed on top of one another on the surface of the substrate (col 2, ll 43-57; col 8, ll 7-9; col 11, ll 30-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that the silane layer comprised multiple monolayers as taught by Sagiv to ensure the entire stent, or substrate, comprised the polymer coating which is applied over the silane layer. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Rowland and Sagiv such that the silane layer comprised 8 to 10 monolayers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Alternatively, it would have been prima facie obvious to try modifying the silane layer of Rowland such that the thickness of the silane layer was 8-10 monolayers in an attempt to provide an improved coated stent as a person with ordinary skill has good reason to pursue the known options within his or her

technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

Response to Arguments

13. Applicant's arguments filed September 22, 2010 have been fully considered but they are not persuasive.

14. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., no biologically active agent attached to the amino-silane layer, radially interior from the coating or within the coating itself) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner notes the combination of Rowland and Yan teach a multi-layered device comprising (from inner layer to outer layer): a catheter, a balloon, a stent, a silane layer, a biologically active agent, and a non-biologically active coating. The non-biologically active coating is disposed on the silane layer even though there is a biologically active agent between at least a portion of the layers.

15. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Yan teaches applying a non-biologically active, bioabsorbable layer

on the outer surface of a biologically active surface of a stent. The outer layer acts as a barrier to prevent premature release of a biologically active agent to alter the release kinetics upon implantation of the stent in the body. Thus, the release of the biologically active agent is delayed until the outer layer is degrades. It would have been obvious to one of skill in the art to modify the device of Rowland to include a non-biologically active, bioabsorbable outer layer to have the advantage of improving the release kinetics of the biologically active agent.

16. Applicant argues Sagiv discloses a silane layer thickness of up to four monolayers, and thus the 8-10 monolayers of Applicant's invention is a surprising and unexpected result. The examiner respectfully disagrees. As noted previously, Applicant acknowledges Sagiv clearly teaches a multilayer silane layer. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. The examiner notes, Applicant has provided no evidence to establish an unobvious difference between the claimed product and the prior art, but rather has merely argued such alleged difference. Mere arguments can not take the place of evidence. *In re Walters*, 168 F.2d 79,80, 77 USPQ 609,610 (CCPA 1948); *In re Cole*, 326 F.2d. 769,773, 140 USPQ 230,233 (CCPA 1964); *In re Schulze*, 346 F.2d 600,602, 145 USPQ 716,718 (CCPA 1965); *In re Lindner*, 457 F.2d 506,508, 173 USPQ 356,358 (CCPA 1972); *In re Pearson*, 494 F.2d 1399,1405, 181 USPQ 641,646 (CCPA 1974); *Meitzner v. Mindick*, 549 F.2d 775,782, 193 USPQ 17,22 (CCPA), cert. Denied, 434 U.S. 854 (1977); *In re DeBlauwe*, 736 F.2d 699,705, 222 USPQ 191,196 (Fed. Cir. 1984).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bates (US 7,611,532), Shah et al. (US 6,830,583), Carlyle et al. (US 2003/0204239), Callol et al. (US 6,174,329), and Cahalan et al. (US 5,782,908) additionally disclose a silane layer disposed on a stent between the stent and an outer coating to improve the adhesion of the coating.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
November 10, 2010

/K. M. D./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776